I. Gonorrhea

A. Examination/Diagnosis

1. History should include documentation of the following:

   a. Any spotting between periods, especially after intercourse ♀

   b. Dyspareunia ♀

   c. Number of partners/any new partners in the last **60** days ♀♂

   d. LMP; any unprotected intercourse since LMP ♀

   e. Method of birth control ♀♂

   f. Any unusual discharge (vaginal or urethral) ♀♂

   g. Any lower abdominal pain ♀

   h. Dysuria ♂

   i. History of oral or anal intercourse ♀♂

2. Examination must be performed prior to treatment with documentation regarding condition of the following:

   a. External genitalia – visual inspection ♀♂

   b. Vagina/cervix – visual inspection ♀

   c. Uterus/ ovaries or scrotal contents – palpation ♀♂

   d. Abdomen ♀

   e. Rectal exam if history includes anal intercourse ♀♂

   f. Throat exam if history includes oral intercourse ♀♂

3. Laboratory procedures - Must be documented

   a. Gonorrhea – Nucleic Acid Amplification Test (NAAT) The following criteria should be used for screening for GC:

      (1) PID work-up ♀

      (2) Contact to GC/NGU/MPC ♀♂

      (3) Symptomatic with mucopurulent cervicitis or urethral discharge ♀♂

      (4) Patient specifically requests ♀♂

      (5) Positive GC test in previous year with no negative GC test post

treatment ♀♂

(6) Pre-IUD insertion ♀

(7) Commercial sex worker ♀♂

(8) Current or recent drug use, including exchanging sex for drugs ♀♂

b. Chlamydia (Nucleic Acid Amplification Test [NAAT]) (See screening criteria for chlamydia in Section II, page 5.)

c. RPR - A serological test for syphilis should be offered to all clients with positive GC tests at the time of the visit for treatment, and before antibiotics are administered. If treatment has already been initiated, RPR should be drawn 6 weeks after completion of treatment.

d. HIV screening is recommended.

B. Treatment Procedure for Uncomplicated Cases (STD Treatment Guidelines, **2006** MMWR, Page 43) Treatment must be documented.

1. Treatment for gonorrhea may be provided except where clients have severe pelvic inflammatory disease or signs of peritonitis. Such cases MUST be referred for expert gynecological management.

2. CDC Recommended Regimens for uncomplicated urethral, endocervical or rectal gonorrhea

- Ceftriaxone 125 mg IM in a single dose
- Cefixime 400 mg. po single dose (Back on the market but may not be available yet to clinics)
- Quinolones such as Cipro and Ofloxacin are **no longer recommended** for the treatment of GC in the United States.

PLUS – if Chlamydia infection has not been ruled out (i.e., no Chlamydia test result)

- Azithromycin 1g po in a single dose, or
- Doxycycline 100 mg po BID for 7 days (contraindicated during pregnancy)

3. See CDC Sexually Transmitted Diseases Treatment Guidelines, 2006 MMWR for alternative treatment regimens for Chlamydia, page 39

4. CDC Recommended Treatment Regimens for Pharyngeal Gonococcal Infections

- Ceftriaxone 125 mg IM in a single dose,

PLUS - if Chlamydia infection has not been ruled out (i.e., no Chlamydia test result)

- Azithromycin 1 g po in a single dose, or
- Doxycycline 100 mg po twice a day for 7 days. (contraindicated during pregnancy)

Gonococcal infections of the pharynx are more difficult to eradicate than infections at urogenital and anorectal sites. Clients who cannot be treated with one of the above must be referred out for treatment.

Not all tests are approved for use in extragenital specimen collection (pharyngeal or rectal). **Please check with your lab before collecting a specimen from one of these sites.** Due to the presence of other Neisseria organisms in the throat or mouth, which may be confused with gonococci, sugar utilization tests must be run on all pharyngeal cultures for definitive diagnosis of gonorrhea.

5. Management of Sex Partners

All sex partners of clients who have gonorrhea should be treated for gonorrhea (and Chlamydia in the absence of a negative Chlamydia test) if their last sexual contact with the client was within **60** days before onset of symptoms or diagnosis of infection in the index client. If a client's last sexual intercourse was **> 60** days before onset of symptoms or diagnosis, the client's most recent sex partner should be treated.

For clients with a lab-confirmed positive gonorrhea, consideration should be given to the use of Expedited Partner Therapy. For information on Expedited Partner Therapy, please turn to page 43, XIV of this (STD) protocol.

C. Education - must be documented

1. Clients should be instructed to avoid sexual intercourse until therapy is completed and they and their partners no longer have symptoms. If one day treatments have been utilized, advise refraining from intercourse for 7 days following treatment. In cases where compliance is doubtful, condom use should be recommended. A supply of condoms should be given to all clients.

2. The client shall be provided information about gonorrhea and the medication prescribed for treatment.

3. The client shall be informed of the complications of untreated gonorrhea, including PID, hospitalization, and infertility for women and epididymitis and prostatitis for men.

D. Follow Up

1. Clients with uncomplicated gonorrhea who have been treated with any of the recommended regimens need not return for a test of cure. However, consider advising the client to be retested 3 months after treatment. If client does not seek retesting in 3 months, encourage retesting if client does present to clinic within the next year.

2. Management of Treatment Failures

   a. Clients who have symptoms that persist after treatment should be evaluated by culture for gonorrhea and any gonococci isolated should be tested for antimicrobial susceptibility.

   b. Infections identified after treatment with one of the recommended regimens usually result from reinfection rather than treatment failure.

3. Standards for Administration of Ceftriaxone

   a. Parenteral ceftriaxone may be provided without the presence of a physician, if there is no known anaphylactic reaction to penicillin.

b. Appropriate resuscitation equipment (i.e., emergency kit, ambu-bag) must be available in the clinic and clinic personnel must be up-to-date in its use if parenteral medication is to be given.

4. Reporting Procedures - State law requires that all cases of gonorrhea be reported by the provider to the Colorado Department of Public Health and Environment (CDPHE). Clinic staff is responsible for completing the state reporting form, including treatment information, (example at the end of this protocol) and faxing it to the STD Registry at the Colorado Department of Public Health and Environment (CDPHE): 303-782-5393. For questions on reporting positive Gonorrhea, call 303-692-2697 at CDPHE.

II. Chlamydia

A. General Information

1. Chlamydial infection occurs more frequently among sexually active adolescents and young adults than among older adults. Asymptomatic infection is common among both women and men.

2. Several important sequelae can result from Chlamydia infection in women including PID, ectopic pregnancy, and infertility. Some women who have apparently uncomplicated cervical infection may already have sub-clinical upper reproductive tract infection. Some men with Chlamydia causing urethritis may experience complications such as epididymitis, prostatitis, and Reiter's syndrome.

B. Examination/Diagnosis

1. History must include documentation of the following:

a. Any spotting between periods, especially after intercourse ♀

b. Dyspareunia ♀

c. Number of partners in the last 2-3 months; any new partners in the last **60** days ♀♂

d. LMP; any unprotected intercourse since LMP ♀

e. Method of birth control; ♀♂

f. Any unusual discharge (vaginal or urethral) ♀♂

g. Any lower abdominal pain ♀

h. Dysuria ♂

i. History of oral or anal intercourse ♀♂

2. Examination must be performed prior to treatment with documentation regarding condition of the following:

a. External genitalia. ♀♂

b. Vagina/cervix – visual inspection ♀

c. Uterus/ ovaries or scrotal contents – palpation ♀♂

d. Abdomen ♀

e. Rectal exam if history includes anal intercourse ♀♂

f. Throat exam if history includes oral intercourse ♀♂

3. Laboratory Procedures

a. A screening test for gonorrhea and Chlamydia must be done in the presence of mucopurulent cervicitis or mucopurulent urethritis.

b. The following women must have a Chlamydia test done routinely at an initial or annual exam. **If the test is not done at the discretion of the provider, there must be documentation as to the reason.** Screening at the initial or annual exam is to be charged on a sliding scale fee schedule that slides to zero. Clients who present for revisits should be tested as indicated by criteria 2 - 6 below. All Chlamydia screening at revisits may be charged as non-required services. Clinics are advised to waive the fee if it is a barrier to testing.

(1) All clients under 25 years, or clients ≥25 with any of the following:

(2) New sex partner in the past **60** days

(3) Multiple sex partners in the past **60** days

(4) Positive Chlamydia test in the past **3** months

(5) Symptomatic (MPC, PID, urethral discharge)

(6) STD contact

c. Evidence is insufficient to recommend routine screening for males. However, such screening should be considered in settings with high prevalence (such as adolescent clinics or STD settings) or for clinics wanting to establish the prevalence in their male client population.

d. **Please check with your lab before collecting a specimen from the anus or pharynx.**

C. Treatment for Chlamydia

1. CDC Recommended Treatment Regimens for Chlamydia

See CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 39.

(Clinical experience and preliminary data suggest that azithromycin is safe and effective during pregnancy.)

- Azithromycin 1 gm po in a single dose, or
- Doxycycline 100 mg PO twice a day for 7 days

2. CDC Alternative Treatment Regimens

See CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 39.

D. Management of Sex Partners

Sex partners should be treated if they had sexual contact with the patient during the 60 days preceding onset of symptoms in the patient or diagnosis of Chlamydia. Providers should treat the most recent sex partner even if the last sexual contact was > 60 days before onset or diagnosis.

For clients with a lab-confirmed positive Chlamydia, consideration should be given to the use of Expedited Partner Therapy. For information on Expedited Partner Therapy, please turn to page 43, XIV of this (STD) protocol.

E. Education - must be documented

1. The client must be advised to refrain from sexual intercourse until she/he and the partner(s) have completed treatment (i.e., 7 days after a single dose regimen or after completion of a 7-day regimen). If compliance is doubtful, condoms should be given for use until 7 days after completion of treatment.

2. The client shall be provided with information about Chlamydia and the medications prescribed for treatment.

F. Follow Up - must be documented

1. Because resistance to the recommended antibiotics for Chlamydia has not been observed, test-of-cure evaluation is not recommended when treatment has been completed. TOC is recommended 3 weeks after treatment when treating pregnant women.

2. The female client should be offered a recheck appointment when the cervix has been noted to be red, swollen and bleeding easily to assure that the cervix is healed. A Pap smear should be done at the recheck visit if the cervix still appears swollen and erythematous.

3. At the next follow-up visit, the client should be questioned about whether the partner(s) received treatment, and counseled about the importance if it has not been done. The CDC Treatment Guidelines encourage re-testing 3 months after treatment due to the frequency of reinfection.

III. Pelvic Inflammatory Disease

A. General Information

1. Pelvic Inflammatory Disease (PID) comprises a spectrum of inflammatory disorders of the upper female genital tract, including any combination of endometritis, salpingitis, tubo-ovarian abscess and pelvic peritonitis. Sexually transmitted organisms such as gonorrhea and chlamydia are implicated in most cases; however, microorganisms that can be a part of the vaginal flora (i.e., anaerobes, G.vaginalis, H. influenzae, enteric Gram-negative rods, and Streptococcus agalactiae) also can be associated with PID. M.hominis, U.urealyticum, and M. genitalium might also be etiologic agents of PID.

2. The clinical diagnosis of PID is imprecise. There exists a higher positive predictive value among sexually active young (especially teenage) women, clients in STD clinics or settings with high rates of gonorrhea and Chlamydia.

3. PID can potentially result in long-term damage to the reproductive system leading to tubo-ovarian abscess, ectopic pregnancy and/or infertility.

B. Examination/Diagnosis

1. Acute PID is difficult to diagnose because of the wide variation in signs and symptoms. Women with PID may be asymptomatic or have subtle/mild symptoms and the resulting delay in diagnosis/ treatment can contribute to inflammatory sequelae in the upper reproductive tract. While laparoscopy can be used to obtain a more complete bacteriologic diagnosis, it is not readily available for acute cases or easily justifiable for use when symptoms are vague or mild. Thus, diagnosis is usually based on clinical findings. Given the sequelae of even mild infections, providers should maintain a low-threshold for the diagnosis of PID.

2. History must include documentation of the following:

   a. Degree, location, onset relative to menses, and course of abdominal pain; any unusual vaginal discharge

   b. History of fever, chills, sweats, GI symptoms, other medical illnesses and allergies.

   c. Recent menstrual history, contraceptive habits, presence or absence of pregnancy symptoms, previous ectopic pregnancy, any spotting between periods or after sex.

   d. Personal history of previous sexually transmitted disease, especially gonorrhea, Chlamydia, or PID.

   e. Partner symptoms of STD's, recent partner change, last episode of intercourse, pain with intercourse; history or anal or oral intercourse.

   f. Clients should be queried about possible contact to sexually transmitted diseases, number of partners in the last year, and any new partners in the last 3 months.

3. Empiric treatment of PID should be initiated in sexually active young women and others at risk for STDs if one or more of the following minimum criteria are present and no other cause for the illness can be identified. Physical exam must include documentation of the presence or absence of the following:

   a. Lower abdominal uterine tenderness

   b. Adnexal tenderness, or

   c. Cervical motion tenderness

4. Additional criteria that support a diagnosis of PID include the following. These might be used to enhance the specificity of the minimum criteria listed previously.

   a. Oral temperature >101°F (38.3°C)

   b. Abnormal cervical or vaginal mucopurulent discharge

   c. Abnormal WBC on saline microscopy of vaginal secretions

d. Elevated erythrocyte sedimentation rate

e. Elevated C-reactive protein

f. Lab documentation cervical infection with gonorrhea or Chlamydia

5. The definitive criteria for diagnosing PID, which are beyond the scope of practice in FP clinics, including the following:

a. Endometrial biopsy with histopathologic evidence of endometritis

b. Transvaginal sonography or other imaging showing signs consistent with PID.

c. Laparoscopic abnormalities consistent with PID.

6. Clients with mild symptoms may be evaluated and treated in the a Title X clinic if the client agrees to return to the clinic in 48-72 hours for follow-up.

7. Laboratory Procedures - must be documented

a. Since there are no reliable clinical criteria to distinguish gonococcal from non-gonococcal PID, endocervical testing for N. gonorrhea is essential. Specimens collected from the anus and pharynx may be tested for N. gonorrhea, as indicated by sexual history. **Please check with your lab before collecting a specimen from the anus or pharynx.**

b. Chlamydia test. **Please check with your lab before collecting a specimen from the anus or pharynx.**

c. Highly sensitive random urine pregnancy test if:

(1) Any menstrual irregularity.

(2) Any pregnancy symptoms, or if client suspects she might be pregnant.

(3) Sexually active without reliable contraception.

(4) Previous ectopic pregnancy.

(5) IUD in place.

d. Serologic test for syphilis and HIV if indicated by history or client request.

C. Treatment Regimens

1. No current data compares the efficacy of parenteral with oral therapy or inpatient with outpatient treatment settings. The decision as to whether hospitalization is indicated should be based on the discretion of the health care provider. Contraindications to treatment in a Title X clinic (clients who must be referred out for possible hospitalization)

a. Surgical emergencies such as appendicitis or ectopic pregnancy cannot be excluded.

b. Pregnancy, even if abortion is planned

c. Client does not respond clinically to oral antimicrobial therapy within 48 hours of outpatient therapy.

d. Client is unable to follow/tolerate an outpatient oral regimen

e. Client has severe illness, N/V, or high fever

f. Suspicion of pelvic abscess or pelvic mass or client with a tubo-ovarian abscess.

g. Since the 2002 Treatment Guidelines, more comprehensive studies have shown that women with HIV have similar symptoms and respond equally well to standard antibiotic regimens. The need for more aggressive interventions in women with HIV has not been demonstrated.

2. Recommended Outpatient Treatment Regimens

(CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 59)

a. Regimen A

- Levofloxacin 500 mg po. once a day x 14 days, or
- Ofloxacin 400 mg po twice a day for 14 days

WITH OR WITHOUT

- Metronidazole 500 mg po twice a day for 14 days

b. Regimen B

- Ceftriaxone 250mg IM single dose

PLUS

- Doxycycline 100 mg po twice a day for 14 days

WITH OR WITHOUT

- Metronidazole 500 mg orally twice a day for 14 days,

3. CDC Alternative Oral Treatment Regimens

See CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 59-60

4. If an IUD is present

a. If an IUD is present, it is an added risk factor. Although the exact effect of removing an IUD on the response of acute salpingitis to antimicrobial therapy and on the risk of recurrent salpingitis is unknown, removal of the IUD **may be considered** at the time of or soon after the initiation of antimicrobial therapy. **If the** IUD is removed, contraceptive counseling is necessary.

b. If the client is at mid-cycle, and has just had intercourse, inform her of the risk of removing the IUD and possible subsequent pregnancy. If the client chooses to leave the IUD in place, documentation must exist, in the client's handwriting, of

her decision to do so. **Close clinical follow up is mandatory.**

c. Antibiotic treatment should be initiated, and the client should be advised to return to the clinic in 2-3 days for re-evaluation. If the client wishes to have the IUD removed, she could return with her next menses for IUD removal. Client must receive information on alternate methods of birth control, and at a minimum be given condoms when IUD is removed. **Future use of an IUD must be given careful consideration, and in any case would not occur for at least three months.**

D. Management of Sex Partners

Sex partners of clients with PID should be treated with regimens effective against both Chlamydia and gonorrhea if they had sexual contact with the client during the **60** days preceding onset of symptoms in the client. **For clients with a lab-confirmed positive Chlamydia, consideration should be given to the use of Expedited Partner Therapy. For information on Expedited Partner Therapy, please turn to page 43, XIV of this (STD) protocol.**

E. Education- Must be documented

1. The client must be advised to refrain from sexual intercourse until 4-7 days after both she and her partner(s) have completed treatment. If compliance is doubtful, she should be counseled to use condoms. A supply should be given.

2. The client must be provided with PID information, a recheck appointment (date and time), and emergency contact information.

3. The client must be provided with information about medications prescribed for treatment.

4. The risk of infertility resulting from PID should also be discussed.

5. The client should be counseled concerning the risk of noncompliance with the treatment schedule including the possible need for surgery if the infection persists/worsens.

F. Follow Up - Must be documented

1. Follow up of clients with mild PID is essential during and after treatment.

a. The client must return within 48-72 hours for a re-check and should be re-examined by the original clinician, if possible. Clients should demonstrate substantial clinical improvement (defervescence, reduction in direct or rebound abdominal tenderness, reduction in uterine, adnexal and cervical motion tenderness).

b. Regardless of the availability of the original clinician or physician, the client must be re-examined in 48-72 hours…If the clinic is unable to schedule the client back in 48 – 72 hours, alternate arrangements must be made with another medical facility/provider.

c. The client must be referred for further evaluation if:

(1) The degree of pelvic pain is unchanged or worse.

(2) The client has not been able to ingest or tolerate the medications prescribed.

(3) A pelvic or adnexal mass has developed since the initial examination.

(4) Fever has not subsided.

d. Attempts should be made to contact clients who miss the 48-72 hour follow-up.

2. TOC

a. Some experts recommend re-screening for gonorrhea and Chlamydia 4-6 weeks after therapy is completed in women with documented infections with these pathogens.

b. Women with acute PID should be offered HIV testing.

3. Rechecking the client after treatment is completed is recommended to ensure complete recovery. The client must be referred for further evaluation if:

a. There is persistent adnexal tenderness.

b. A new adnexal or pelvic mass has developed.

4. If the client does not return for the 48-72 hour appointment and returns later to the clinic for continued supplies or care, she should be questioned regarding the following:

a. Persistence of any of her PID symptoms

b. Completion of her therapy

c. Notification/treatment of her partner(s) if indicated.

She should be examined if there is any evidence of incomplete resolution of her PID.

IV. Mucopurulent Cervicitis (MPC)

A. General Information

1. MPC may be characterized by a purulent or mucopurulent endocervical exudate visible in the endocervical canal or on an endocervical swab specimen, and/or experienced as abnormal vaginal discharge. Easily induced cervical bleeding is also a hallmark and may result in post-coital bleeding. However, MPC is most often asymptomatic.

2. MPC can be caused by Chlamydia or gonorrhea, however, in most cases, neither organism will be isolated. Clients with MPC should be tested for these two infections; however, MPC is not a sensitive predictor of infection with these organisms, because most women with Chlamydia or gonorrhea do not have MPC.

B. Examination/Diagnosis

1. History must include documentation of the following:

a. Any spotting between periods, especially after intercourse

b. Dyspareunia

c. Number of partners in the last **60** days; any new partners in the last **60** days

d. LMP; method of birth control; any unprotected intercourse since LMP

e. Any unusual vaginal discharge

f. Any lower abdominal pain

2. A pelvic examination must be performed prior to treatment with documentation regarding condition of the following:

a. External genitalia.

b. Vagina and cervix.

c. Ovaries and uterus.

d. Abdomen.

3. Laboratory Procedures

A screening test for gonorrhea and Chlamydia must be done in the presence of mucopurulent cervicitis.

C. Treatment for MPC

1. The results of testing for gonorrhea and Chlamydia should determine the need for treatment, unless the likelihood of infection with either organism is high or the client is unlikely to return for treatment.

2. Empiric treatment for Chlamydia should be considered for women at increased risk of this infection. (Concurrent treatment for gonorrhea should be given if the prevalence of that infection is high [>5%] in that clinic's population.)

- Azithromycin 1 gm orally in single dose, or
- Doxycycline 100 mg PO twice a day for 7 days (only if pregnancy can be ruled out)

3. After the possibilities of relapse and reinfection have been excluded, management of persistent MPC is unclear. In such cases, additional antimicrobial therapy may be of little benefit. However, many clinicians will still try a course of Doxycycline. Attempts to acidify the vagina may also be successful.

D. Management of Sex Partners

Sex partners of women treated for MPC should be notified, examined and treated for the STD suspected in the index client. If an STD is NOT identified in the index client, partner treatment is unnecessary. **If either Chlamydia or gonorrhea is identified in the index client,** (**lab-confirmed), consideration should be given to the use of Expedited Partner Therapy. For information on Expedited Partner Therapy, please turn to page 43, XIV of this (STD) protocol.**

E. Education - must be documented

1. The client must be advised to refrain from sexual intercourse until she and her partner(s) have completed treatment (i.e., 7 days after a single dose regimen or after completion of a 7-day regimen). If compliance is doubtful, condoms should be given for use until 7 days after completion of treatment.

2. The client shall be provided with information about MPC, Chlamydia and the medications prescribed for treatment.

F. Follow Up- must be documented

Follow up should be done in accordance with the infection for which the woman is treated. She should be instructed to return for reevaluation if symptoms persist.

V. Urethritis including NGU (Nongonococcal Urethritis) ♂

A. Examination/Diagnosis - characterized by urethral inflammation

1. History must include documentation of the following:

a. Known contact to partner with diagnosis of Chlamydia or gonorrhea.

b. Number of partners/any new partners in the last 60 days.

c. Mucopurulent discharge; urethral itching; dysuria – presence and duration.

d. Use of condoms.

2. An external genital examination must be performed prior to treatment

3. Laboratory procedures - Must be documented

a. Screening for gonorrhea and Chlamydia.

b. Microscopic exam of first void urine sediment demonstrating $\geq$10 WBC per high power field.

c. Gram stain of urethral secretions, if available

B. Treat confirmed infections with the appropriate CDC Recommended Treatment Regimens

CDC **2006** MMWR Sexually Transmitted Diseases Treatment Guidelines, page 36.

C. Education

1. The client shall be provided with information about urethritis, NGU, Chlamydia as appropriate.

2. The client shall be provided with information prescribed for treatment.

3. The client must be instructed to abstain from intercourse until treatment is complete or for 7 days after single dose therapy. If compliance is unlikely, then she should be instructed to

use condoms. A supply should be given.

D. Follow Up

1. All contacts to urethritis or NGU within the last 60 days should be referred for evaluation and treatment.

2. If symptoms persist or recur, clients should be instructed to return to the clinic. Persistence of symptoms beyond three months may indicate chronic prostatitis/chronic pelvic pain syndrome in men.

3. In the absence of Chlamydia and gonorrhea, consider other infectious organisms. Please refer to CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 36.

VI. Syphilis

A. General Information

1. Syphilis may be an acute or chronic systemic disease characterized initially by a painless lesion on the skin or mucous membranes. Manifestations of secondary infection (rash, mucocutaneous lesions, adenopathy) and tertiary infection (cardiac, neurologic, ophthalmic, auditory and gummatous lesions) may also be present. Latent infections (those lacking clinical manifestations) are detected by serologic testing. Latent syphilis acquired within the preceding year is called "early latent" syphilis. All other cases of latent syphilis are either "late latent" syphilis or syphilis of unknown duration.

2. The mode of transmission is by direct contact with exudate (saliva, semen, blood, vaginal discharge) of infected persons during infectious periods. The incubation period is 10 - 90 days with a variable communicability. Infection occurs by a spirochete organism, Treponema *pallidum*.

B. Examination/Diagnosis

1. History must include documentation of the following:

a. Whether or not there is known sexual exposure to a person with a diagnosis of syphilis (even if patient is asymptomatic).

b. Any history of a painless skin lesion (chancre) on the genital, mouth, or anal area. Appearance of the lesion usually occurs about three weeks after contact.

c. Any complaint of symptoms of other sexually transmitted infections.

d. Number of partners in last 2-3 months; new partner in the last 2-3 months.

2. Physical exam and documentation regarding:

a. Evidence of lesion, which is oval, ulcerated and indurated, with bilateral inguinal lymphadenopathy.

b. Presence of skin rash, mucus patches, and/or splenomegaly.

c. Clients with questionable genital skin lesions may raise suspicion for condyloma lata.

3. Laboratory Testing - Must be documented

   a. Persons for whom there is a reasonable suspicion of syphilis should be screened by laboratory examination.

   b. Darkfield examinations and direct fluorescent antibody tests of lesion exudate are the definitive methods for diagnosing early syphilis.

   c. Two types of blood tests are necessary for presumptive diagnosis of syphilis:

      (1) Non-treponemal (e.g., Venereal Disease Research Laboratory [VDRL], rapid plasma reagin [RPR]).

      VDRL or RPR becomes positive 14-90 days after contact or 7-10 days after appearance of the chancre. All serologic tests can be negative early in infection and, thus, primary syphilis cannot be ruled out.

      (2) Treponemal (e.g., fluorescent treponemal antibody absorbed [FTA-ABS]).

   d. Submission to the state health laboratory is low cost. A VDRL or RPR will be done, and if positive a FTA-ABS will be performed to detect specific antibody.

   e. Interpretation of Results

      (1) Reagin weakly reactive or reactive; FTA-ABS reactive

      These results usually indicate syphilis. Tests should always be repeated on a new specimen if doubt exists.

      (2) Reagin weakly reactive or reactive; FTA-ABS non-reactive

      False Positive non-treponemal tests may occur whenever there is a strong immunologic stimulus secondary to: infections, immunizations, autoimmune diseases, inflammatory disease, chronic liver disease, rheumatic heart disease, IV drug use, pregnancy or aging.

      (3) Reagin non-reactive; FTA-ABS not done

      Treponemal tests are not indicated unless late syphilis is suspected on clinical grounds. A reactive FTA-ABS test would add weight to the diagnosis of late syphilis.

      (4) Other results

   Clients with primary syphilis may have one or both of the serologic tests non-reactive when first seen. However, if there is a history of possible contact to syphilis or a suspicious lesion, repeat the VDRL/RPR 4-6 weeks after the baseline test.

   The FTA-ABS test will remain reactive after treatment of early latent, secondary, and most cases of primary syphilis.

   Non-reactive serologic tests and normal clinical evaluation cannot exclude incubating syphilis.

Caution: Serologic tests provide only indirect evidence of syphilis and may be reactive in the absence of clinical, historical, or epidemiological evidence of syphilis. Therefore, careful clinical interpretation of test results and other evidence is necessary for proper diagnosis.

f. Testing for other STDs, including HIV, is recommended.

C. Treatment

1. If exposure to syphilis occurred within the previous 90 days, the client may be seronegative yet infected; therefore, presumptive treatment may be chosen if compliance and follow-up is uncertain.

2. Treatment for late latent and tertiary syphilis theoretically may require a longer duration of therapy.

3. CDC Recommended Regimen for Primary or Secondary Syphilis

Benzathine Penicillin G 2.4 million units IM in one dose.

Pregnant patients allergic to penicillin should be referred for skin testing/ desensitization, as Penicillin G is the only therapy with documented efficacy during pregnancy.

4. CDC Alternative Regimens for Penicillin allergic clients (nonpregnant).

See CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 25.

5. CDC Treatment for Latent Syphilis

See CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 26.

D. Management of Sex Partners

All known sex partners must be notified and receive treatment.

E. Education

1. The client should be provided with information about syphilis and medication prescribed for treatment.

2. The client should be warned of the possibility of Jarisch-Herxheimer reaction, which may occur in the first 24 hours following treatment. It is characterized by an acute febrile reaction often accompanied by headache and myalgia. Antipyretics may be recommended.

3. Instruct the client on the use of condoms with sexual activity.

F. Follow-Up

1. Treatment failures can occur with any regimen. Assessing response to treatment is often difficult and no definitive criteria for cure or failure have been established.

a. Follow-up testing should be performed with the same test utilized for the initial diagnosis.

b. Clients should be re-examined both clinically and serologically at both 6 and 12 months. Serologic test titers (VDRL or RPR) may decline more slowly for clients who previously had syphilis. Failure of non-treponemal test titers to decline fourfold within 6 months after treatment indicates failed treatment or reinfection.

(1) These clients should be re-evaluated for HIV infection. HIV infected clients should be evaluated more frequently, at 3-month intervals instead of 6-month intervals.

(2) Additional clinical and serologic follow-up is indicated. If follow-up cannot be assured, re-treatment* is recommended. Some experts also recommend CSF to rule out an unrecognized CNS infection.

c. Clients who have signs and symptoms that persist or recur or who have sustained a fourfold increase in non-treponemal test titers, probably failed treatment or were re-infected. These clients should be re-treated* after re-evaluation for HIV. Unless reinfection is certain, a lumbar puncture should also be performed.

d. *Experts recommend re-treatment with three weekly injections of benzathine penicillin G 2.4 million units IM, unless CSF examination indicates neurosyphylis.

2. If preferred, the client may be referred out of the site for treatment of positive syphilis. Appropriate referral and follow-up should be completed.

3. Compliance with state reporting requirements is mandatory.

VII. Vaginitis and Vulvitis

A. Bacterial Vaginosis

1. Examination/Diagnosis

a. History must include documentation of the following:

(1) Duration of the discharge

(2) Characteristics of the discharge - color, odor

(3) Presence of itching or burning (vaginal or external)

(4) Dyspareunia or lower abdominal pain, dysuria

(5) Use of any over-the-counter treatment

b. A pelvic examination must be performed prior to treatment with documentation regarding condition of the following:

(1) External genitalia.

(2) Vagina, cervix.

(3) Ovaries, uterus.

(4) Abdomen.

c. Laboratory procedures - Must be documented

(1) Offer a screening test for gonorrhea and Chlamydia, if she is at risk.

(2) Wet prep should be done.

(3) pH of vaginal fluid

d. Clinical diagnosis is made when three of four of the following criteria are present and documented:

(1) Positive "whiff" test (elaboration of pungent, fishy odor when vaginal discharged is mixed with 10% KOH).

(2) Elevated vaginal fluid pH >4.5.

(3) Presence of thin, malodorous, homogeneous discharge, grayish/white in color.

(4) Presence of "clue cells" on wet prep (microscopic exam).

2. Treatment

a. CDC recommended treatment regimens for symptomatic non-pregnant women

- Metronidazole 500 mg, po, twice a day for 7 days, or
- Metronidazole gel 0.75%, one applicator (5g) intravaginally once a day for 5 days, or
- Clindamycin cream 2%, one applicator (5g) intravaginally at bedtime for 7 days

b. CDC Alternative Treatment Regimens

See CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 51.

3. Management of Sex Partners

Clinical trials indicate that response to treatment and the likelihood of relapse or recurrence are not affected by treatment of the sex partner. Routine treatment of sex partners is not recommended.

4. Bacterial Vaginosis in Pregnant Women

BV has been associated with adverse pregnancy outcomes, such as premature rupture of the membranes, preterm labor and preterm birth. According to ACOG and CDC guidelines, BV screening should be considered in women at high risk for preterm labor.

CDC Recommended Treatment Regimens for Pregnant Women

- Metronidazole 500 mg po twice a day for 7 days, or
- Metronidazole 250 mg po three times a day for 7 days, or
- Clindamycin 300 mg po twice a day for 7 days

5. Education

   a. The client should be provided with information about BV, vaginitis and the medication prescribed for treatment.

   b. In the case of unprotected intercourse or questionable history, pregnancy should be ruled out.

   c. The client should either abstain from sexual intercourse or use condoms during treatment if she is experiencing irritation.

   d. The client should be advised to avoid any alcohol during and for 24 hours after completion of metronidazole.

6. Follow-Up

   a. The patient should be offered a recheck appointment in the clinic if symptoms do not resolve following therapy.

   b. Recurrence of BV is not unusual and re-treatment may be necessary.

B. Vulvovaginal candidiasis (VVC)

1. General Information

   Although not generally considered a sexually transmitted disease, VVC is included in these guidelines because it is frequently diagnosed in women presenting with genital symptoms.

2. Causative Agent

   VVC is the common infection caused by *Candida albicans*, or other *Candida* sp., a fungal parasite. The incubation period is 2-5 days. Symptoms include itching and a white curd-like discharge.

3. Examination/Diagnosis

   a. History must include documentation of the following:

      (1) Duration of the discharge

      (2) Characteristics of the discharge - color, odor

      (3) Presence of itching or burning - vaginal, external

      (4) Dyspareunia, lower abdominal pain, dysuria

      (5) Recent use of antibiotics

(6) Use of any over-the-counter treatment

(7) Risk factors for diabetes

b. A pelvic examination must be performed prior to treatment, with documentation regarding condition of the following:

(1) External genitalia

(2) Vagina, cervix

(3) Ovaries, uterus

(4) Abdomen

c. Laboratory Procedures - Must be documented

Wet prep should be done, including pH of vaginal fluids

d. Suggestive diagnosis - thick or "cheesy" vaginal discharge; adherent exudative plaques on the vaginal mucosa; vulvar/vaginal pruritis/soreness; vulvar burning, perineal dysuria, vulvar and geographic erythema with kissing lesions, edema, and/or erosions of the external genitalia; pH < 4.5; satellite lesions.

e. Definitive diagnosis

(1) Demonstration of fungal elements (budding yeast or pseudomycelia) in KOH preparation, VIP (purple) stain, or Gram stain.

(2) Positive culture

4. CDC Recommended Treatment Regimens

- Butoconazole 2% cream 5g intravaginally for 3 days+, or
- Butoconazole 2% cream 5g (Butoconazole-sustained release) single intravaginal application, or
- Clotrimazole 1% cream 5g intravaginally at bedtime for 7-14 days+, or
- Clotrimazole 100mg vaginal tablet, intravaginally at bedtime for 7 days+, or
- Clotrimazole 100mg vaginal tablet, 2 tablets intravaginally, at bedtime for 3 days, or
- Miconazole 2% cream 5g intravaginally at bedtime for 7 days+ or
- Miconazole 100 mg vaginal suppository one intravaginally at bedtime for 7 days+, or
- Miconazole 200mg vaginal suppository, one intravaginally, at bedtime for 3 days+, or
- Miconazole 1200mg vaginal suppository, one intravaginally for 1 days+, or

- Nystatin 100,000-unit vaginal tablet, one tablet for 14 days, or
- Tioconazole 6.5% ointment 5g intravaginally in a single application+, or
- Terconazole 0.4% cream 5g intravaginally for 7 days, or
- Terconazole 0.8% cream 5g intravaginally for 3 days, or
- Terconazole 80mg vaginal suppository, one suppository for 3 days, or
- Fluconazole 150mg oral tablet, one tablet in a single dose.

NOTE: (+) Indicates over-the-counter preparation

a. The following drugs might interact (elevate liver enzymes) with fluconazole **(not an exhaustive list – be sure to check any specific drug the client is on)**:

(1) Antihistamines (Hismanal, Seldane)

(2) Theophylline

(3) Antacids, H2-receptor antagonists (Tagamet), gastric acid-pump inhibitors (Prilosec)

(4) Antiepileptics (Dilantin, Tegretol)

(5) Rifampin, isoniazid

(6) Oral hypoglycemic agents

(7) Digoxin, hydrochlorothiazide

(8) Anticoagulants (Coumadin)

b. Self-medication with OTC preparations should be advised only for women who have been diagnosed previously with VVC and who have a recurrence of the same symptoms. Any woman whose symptoms persist or who has a recurrence of symptoms within two months of OTC treatment should seek medical care.

c. Uncomplicated VVC (mild-moderate symptoms, sporadic, non-recurrent in a normal host with normally susceptible C.albicans) responds to all azoles, including short-term (<7 day) and single-dose regimens.

d. Complicated VVC (severe, local or recurrent VVC in an abnormal host, i.e., diabetic, C.glabrata infection) requires a longer duration of therapy (i.e., 7-14 days) with either topical or oral azoles.

e. Treatment in pregnant women:

Only topical azole therapies used for 7 days should be recommended to treat pregnant women.

5. Management of Sex Partners

a. VVC is not usually acquired through sexual intercourse. Treatment of sex

partners is not recommended but may be considered for women with recurrent infection.

b. Some men may have balanitis, which is characterized by erythematous areas on the glans in conjunction with pruritis or irritation. These partners might benefit from treatment with topical antifungal agents.

6. Education

a. The client shall be provided with information about candida, vaginitis and the medications prescribed for treatment.

b. Basic hygiene instructions should be discussed, i.e., wear cotton panties, avoid tight pants/jeans, avoid perfumed vaginal products and sprays.

c. The client should abstain from sexual intercourse if she is experiencing itching or irritation.

7. Follow up

The client should be offered a recheck appointment in the clinic following therapy, if symptoms do not resolve or if symptoms recur within 2 months.

8. Recurrent VVC - 4 or more episodes of symptomatic VVC annually.

a. Etiology

(1) The pathogenesis is poorly understood.

(2) Risk factors for recurrent VVC include uncontrolled diabetes mellitus, immunosuppression, and corticosteroid use. Most women have no apparent predisposing factors.

b. Treatment

(1) Optimal treatment has not been established. An initial intensive regimen continued for 7-14 days, followed immediately by a maintenance regimen for at least 6 months is recommended. All cases of recurrent VVC should be confirmed by culture before maintenance therapy is initiated.

(2) Oral fluconazole, 100mg, 150 mg, or 200 mg weekly for six months is the first line of treatment.

(3) Recurrent non-albicans VVC **(as diagnosed by culture)** may respond to 600 mg boric acid in gelatin capsule, administered vaginally qd X2 weeks.

(4) Routine HIV screening for women with recurrent VVC, in the absence of HIV risk factors, is unnecessary. Studies are underway to confirm an alleged increase in the incidence of VVC in HIV-infected women.

c. Management of Sex Partners

Routine treatment of sex partners is unnecessary but may be considered for partners who have symptomatic balanitis or penile dermatitis.

d. Follow Up

Regular follow-up evaluations should be conducted to monitor the effectiveness of therapy and the occurrence of side effects.

C. Trichomonas Vaginalis

1. General Information

a. Trichomonas, caused by a motile protozoan, is a common vaginal pathogen. The incubation period is about 7 days.

b. Most women are symptomatic. Most men who are infected do not have symptoms.

2. Examination/Diagnosis

a. History should include documentation of the following:

(1) Duration of discharge

(2) Characteristics of discharge - color, odor

(3) Presence of itching or burning - vaginal, external

(4) Dyspareunia; lower abdominal pain; dysuria

(5) Use of any over-the-counter treatment

b. A pelvic examination must be performed prior to treatment with documentation regarding condition of the following:

(1) External genitalia.

(2) Vagina, cervix.

(3) Ovaries, uterus.

(4) Abdomen.

c. Laboratory procedures - Must be documented

(1) Should be offered testing for GC, Chlamydia, syphilis and HIV.

(2) Wet prep should be done

(3) pH of vaginal fluid

d. Suggestive diagnosis: Diffuse, malodorous, yellow-green discharge with vulvar irritation; a profuse white, yellow, or green malodorous vaginal discharge (frothy leukorrhea); an edematous, friable cervix with punctate area of exudation or subepithelial hemorrhages (strawberry cervix); perineal dysuria and external genital irritation; pH$\geq$5.0.

e. Definite diagnosis

(1) Wet Prep - demonstration of motile trichomonads on saline mount of vaginal exudate or on examination of urine sediment,

(2) Incidental identification on Pap smear or Gram stain;

(3) Positive culture.

3. CDC Recommended Treatment (including pregnant women)

- Metronidazole 2g po in a single dose, or
- Tinidazole 2 g po in a single dose

4. CDC Alternative Treatment Regimen

See CDC **2006** MMWR Sexually Transmitted Diseases Treatment Guidelines, page 52.

5. Management of Sex Partners

Sex partners should be treated. Clients should be instructed to avoid sex until treatment has been completed and the client and her partner are asymptomatic.

6. Education

a. The client shall be provided with information about Trich. vaginitis and the medication prescribed for treatment.

b. The client and her partner should be advised to avoid any alcohol during and for 24-48 hours after completion of metronidazole.

7. Follow Up

a. Follow-up is unnecessary for those who become asymptomatic after treatment or who are initially asymptomatic.

b. Treatment failures

(1) If failure occurs with metronidazole 2 g, the client should be treated with metronidazole 500 mg, po twice a day for 7 days or tinidazole 2 g po single dose.

(2) If repeated failure occurs, the client should be treated with metronidazole 2g or tinidazole 2 g, po, in a single dose, once daily for 5 days.

VIII. Herpes

A. General Information

1. Genital herpes is a recurrent, incurable viral disease. Two serotypes of HSV have been identified: HSV-1 and HSV-2. Most cases of recurrent genital herpes are caused by HSV-2. Herpes viruses are chronic, persistent viruses that infect the nerve ganglions.

2. Most HSV-2 infected persons have not received a diagnosis of genital herpes. Such persons have mild or unrecognized infections that shed virus intermittently in the genital tract. Many cases of genital herpes are transmitted by persons who are unaware that they have the infection or are asymptomatic when transmission occurs.

3. The possibility of other co-existing STD's should also be considered.

4. Systemic antiviral drugs partially control the symptoms and decrease the risk of transmission to uninfected partners. However, these drugs neither eradicate latent virus nor affect the risk, frequency or severity of recurrences after the drug is discontinued.

B. Examination/Diagnosis

1. History of the following must be documented:

   a. Onset of symptoms

   b. Location of lesions

   c. Any previous history of similar symptoms?

   d. Number of current partners? Any new partners in last month? Any partners with similar lesions?

   e. Any relief measures tried? Any results?

2. Physical exam must include documentation of the following:

   a. Observation and diagnosis of lesions.

   b. Palpation of inguinal lymph nodes.

   c. A thorough speculum and bimanual exam may have to be deferred due to client discomfort. When it is feasible, the examination should be done.

3. Laboratory procedures - Must be documented

   a. If a speculum exam is possible, a wet prep should be done, if indicated and testing for other STDs, including HIV, offered.

   b. A culture of the lesion may be done for diagnostic purposes, especially during an initial outbreak or in cases where the diagnosis has never been confirmed by culture. Viral culture isolates should be typed for HSV-1 vs. HSV-2. Diagnosis is enhanced by viral recovery from vesicles (95%) vs. ulcers (70%).

   c. Serologic testing to distinguish HSV-1 from HSV-2 is available. Be sure to request serologic type-specific glycoprotein G (gG)-based assays. (CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 16)

4. Diagnosis

   a. Small, clear, grouped vesicles on red base. Primary infections complicated by systemic viremic symptoms (fever, HA, malaise, myalgia, stiff neck) in 40-70% of cases. Local symptoms last 10-21 days.

   b. History of vesicles as described above, plus presence of superficial, usually

tender, ulcerated lesions.

c. History of recurrent lesions in the same site, plus superficial tender lesions. Recurrences are often preceded by a prodrome of localized tingling or irritation of the vulva or sacral itching 12-24 hours before the onset of lesions. Duration of lesions (5-10 days) and viral shedding (3-5 days) is shorter than with primary infections.

d. Inguinal adenopathy (firm, tender nodes) may be present with any of the above presentations.

C. CDC Recommended Treatment Regimens for first clinical episode

- Acyclovir 400mg po three times a day for 7-10 days, or
- Acyclovir 200mg po five times a day for 7-10 days, or
- Famciclovir 250mg po three times a day for 7-10 days, or
- Valacyclovir 1g po twice a day for 7-10 days

NOTE: Treatment may be extended if healing is incomplete after ten days of therapy. The use of topical therapy with acyclovir is discouraged, as it is substantially less effective than the systemic regimen.

D. CDC Recommended Treatment Regimens for Episodic, Recurrent HSV

See CDC **2006** MMWR Sexually Transmitted Diseases Treatment Guidelines, page 18.

E. CDC Recommended Regimens for Daily Suppressive Therapy

- Acyclovir 400 mg po twice a day, or
- Famciclovir 250 mg po twice a day, or
- Valacyclovir 500 mg po once a day*, or
- Valacyclovir 1gram po once a day
- This regimen appears to be less effective in clients with very frequent recurrences (i.e., >10 episodes/year).

1. Daily suppressive therapy reduces the frequency of genital herpes recurrences by >75% among clients with frequent recurrences (i.e., 6 or more recurrences per year).

2. Safety and efficacy have been documented among clients receiving daily therapy with acyclovir for as long as 6 years, and with valacyclovir and famciclovir for 1 year.

3. After 1 year of continuous suppressive therapy, discontinuation of therapy should be discussed as the frequency of recurrences decreases over time in many clients.

4. Suppressive therapy reduces but does not eliminate asymptomatic viral shedding.

F. Treatment during Pregnancy

1. The safety of systemic acyclovir, valacyclovir, and famciclovir therapy in pregnant women has not been definitively established. Available data do not indicate an increase in birth defects in the group exposed to acyclovir in the first trimester when compared to the general population. Information relative to valacyclovir and famciclovir use during pregnancy is too limited to establish safety and efficacy.

2. Acyclovir may be administered orally to pregnant women with primary genital herpes infection or severe recurrent herpes. There is no data to support the use of antiviral therapy in seropositive women without a history of genital herpes.

G. Management of Sex Partners

1. Sex partners are likely to benefit from counseling. Symptomatic sex partners should be evaluated and treated in the same manner as clients who have genital lesions.

2. Most people with genital HSV infection do not have a history of typical genital lesions. Even asymptomatic sex partners of clients who are newly diagnosed with genital herpes should be questioned concerning their histories of genital lesions, should be encouraged to examine themselves for lesions in the future and seek medical attention promptly if lesions appear.

H. Education

1. The client must be provided with information about genital herpes and antiviral medications.

2. Clients should be given information about the natural history of the disease, potential for recurrent episodes, asymptomatic viral shedding and sexual transmission.

3. Clients should be advised to abstain from sexual activity when lesions or prodromal symptoms are present and encouraged to inform their sex partners of their diagnosis. The use of condoms during all sexual exposures with new or uninfected sex partners should be encouraged.

4. Sexual transmission of HSV can occur during asymptomatic periods. Asymptomatic viral shedding occurs more frequently in clients who have genital HSV-2 infection than HSV-1 infection and in those who have had genital herpes for <12 months.

5. The risk of neonatal infection should be explained to all clients. Childbearing-age women who have genital herpes should be advised to inform their prenatal health care providers about their HSV status.

6. Clients experiencing an initial infection should be advised that episodic antiviral therapy during recurrent episodes might shorten the duration of lesions and suppressive antiviral therapy can ameliorate or prevent recurrent outbreaks.

I. Follow Up

1. A client with acute, severe infection or secondary superinfection may need to be referred for private care.

2. The client should be instructed to seek medical attention immediately if unable to urinate.

IX. Pubic Lice

A. General Information

This parasitic infection occurs most often in the pubic hair. However, it may spread to the axillae, trunk, anus, legs and occasionally to eyelashes, and in men, beard, and moustache, if left untreated.

B. Causative Agent

Pediculosis pubis (crab lice) is caused by an ectoparasite. This disease can be spread by sexual and nonsexual contact, including bedding and clothing. The incubation period is one week for the eggs to hatch and two weeks for the mature lice to appear. Symptoms include pruritis, blue spots, sores, grey-white lice, and hair nits.

C. Examination/Diagnosis

1. History of the following must be documented:

   a. Onset of symptoms

   b. Any known exposure to lice

   c. Any co-existing symptoms of vaginitis

2. Physical exam must include documentation of the following:

   a. Positive observation of pubic lice prior to treatment.

   b. A bimanual examination on any client with lice who is complaining of symptoms indicating the possibility of other pelvic pathology (PID, herpes, UTI, vaginitis).

3. Laboratory procedures - must be documented

   a. Microscopic diagnosis, if indicated:

      (1) Cut hair with nit attached and fasten to slide with tape.

      (2) Examine under microscope. Adult lice can also be examined microscopically.

   b. Clients should be offered a screening test for gonorrhea and Chlamydia, and a wet prep, if indicated.

D. CDC Recommended Treatment Regimens

1. Permethrin 1% cream rinse applied to affected areas and washed off after 10 minutes.

   Permethrin has less potential for toxicity than lindane.

2. Lindane 1% Shampoo is not recommended as a first line therapy due to toxicity concerns. It should only be used as an alternative if other treatment has failed.

a. Not recommended for pregnant or lactating women or for children <2 years old.

b. Should be applied for 4 minutes to the affected area and then thoroughly washed off.

c. Lindane is the least expensive therapy; toxicity, as indicated by seizure and aplastic anemia, has not been reported when treatment has been limited to the 4-minute period.

3. Pyrethrins with piperonyl butoxide applied to the affected area and washed off after 10 minutes.

4. Over-the-counter medications containing pyrethrins and piperonly butoxide, such as Rid liquid, A-200 shampoo, R & C Shampoo, and Triple-X Shampoo may be recommended if the client does not want to be seen in the clinic.

5. Clients with pubic lice in the eyelashes should be referred to an opthamologist for treatment with an occlusive opthalmic ointment.

E. CDC Recommended Treatment Regimens for Pregnant/Lactating Women

1. Permethrin 1% cream rinse or Pyrethrins with piperonyl butoxide applied to affected areas and washed off after 10 minutes.

2. Over-the counter regimens containing pyrethrins and piperonyl butoxide, such as Rid liquid, A-200 shampoo, R&C shampoo and Triple-X shampoo may be used.

F. Management of Sex Partners

Sex partners within the preceding month should be treated.

G. Follow Up

1. Clients should be re-evaluated after 1 week if symptoms persist. A re-check appointment may be offered.

2. Re-treatment may be necessary if lice are found or if eggs are observed at the hair-skin junction. Clients who do not respond to one of the recommended regimens should be re-treated with an alternative regimen.

H. Education

1. The client must be provided with information on pubic lice and the medications prescribed for treatment.

2. Bedding and clothing should be decontaminated (i.e., either machine-washed or machine-dried using the heat cycle or dry-cleaned) or removed from body contact for at least 72 hours. Fumigation of living areas is not necessary.

X. Condyloma Acuminata (HPV, Human Papilloma Virus, Genital Warts)

A. General Information

1. More than 30 types of HPV can infect the genital tract. Most HPV infections are asymptomatic, sub-clinical or unrecognized. HPV types 6 or 11 usually cause visible genital warts. Other HPV types in the anogenital region (types 16, 18, 31, 33 and 35) have been strongly associated with cervical dysplasia. However, women with visible genital warts can be infected simultaneously with multiple HPV types.

2. Sub-clinical genital HPV infection occurs more frequently than visible genital warts among men and women. Infection is often indirectly diagnosed on the cervix by Pap smear, colposcopy or biopsy. The use of acetic acid to detect sub-clinical or aceto-white genital warts is not recommended, as aceto-whitening is not a specific test for HPV infection. A definitive diagnosis of HPV infection depends on detection of viral nucleic acid (DNA or RNA) or capsid protein. Pap smear diagnosis of HPV does not always correlate with detection of HPV DNA in cervical cells. Cell changes attributable to HPV in the cervix are similar to those of mild dysplasia and often regress spontaneously without treatment. Screening for HPV infection using DNA or RNA tests (Digene Hybrid Capture 2) is not recommended except as outlined in the American Society for Colposcopy and Cervical Pathology guidelines referenced in the Pap Smear Screening and Follow Up protocol of this manual.

B. Causative Agent

1. Genital and anal warts are caused by the human papilloma virus (HPV). The incubation period is unclear; probably 3 weeks - 8 months.

2. Depending on the size and anatomic location, genital warts can be pruritic, friable, painful or asymptomatic. Genital warts have a tendency to proliferate and become friable during pregnancy.

C. Examination/Diagnosis

1. History should include documentation of the following:

   a. Onset of lesions ♀♂

   b. Presence of co-existing itching/irritation ♀♂

   c. Whether or not partner(s) has similar lesions ♀♂

   d. Previous history of similar symptoms ♀♂

   e. History of abnormal Pap smear ♀

   f. History of diabetes ♀♂

   g. History of immunosuppression ♀♂

2. Pelvic examination must be performed at the time of treatment with external genitalia examined monthly as long as treatment continues. Document the condition of the following:

   a. External genitalia including positive observation, number, location and size of warts. ♀♂

   b. Vagina, cervix ♀

c. Anal area ♀♂

3. Laboratory procedures

a. A wet prep may be done to assess the possibility of coexisting vaginitis at the time of diagnosis. ♀

b. Assure that the client is up to date in her Pap smear screening. ♀

c. The client should be offered screening tests for gonorrhea, Chlamydia, HIV, and syphilis. ♀♂

D. Treatment

1. No evidence indicates that currently available treatments eradicate or affect the natural history of HPV infection. The removal of warts may or may not decrease infectivity. If left untreated, visible genital warts may resolve on their own, remain unchanged, or increase in size or number. No evidence indicates that treatment of visible genital warts affects the development of cervical cancer.

2. Treatment is not recommended for sub-clinical HPV infection. HPV has been demonstrated in adjacent tissue after laser treatment of HPV-associated dysplasia and after attempts to eliminate sub-clinical HPV by extensive laser vaporization of the anogential area. In the presence of co-existing dysplasia, management should be based on the grade of dysplasia.

3. CDC Recommended Treatment Regimens for External Genital Warts

Provider-Administered:

Cryotherapy with liquid nitrogen or cryoprobe. Repeat applications every 1-2 weeks.

a. Warts are destroyed by thermal-induced cytolysis. Proper use requires substantial training to avoid over or under-treatment.

b. Pain after application, followed by necrosis and sometimes blistering, are common.

OR

Podophyllin resin 10-25% in compound tincture of benzoin.

c. A small amount should be applied to each wart and allowed to air dry. To avoid systemic absorption and toxicity, application should be limited to ≤0.5ml of podophyllin per session. The preparation should be thoroughly washed off 1-4 hours after application to reduce local irritation. Repeat weekly if necessary.

d. The safety of podophyllin during pregnancy has not been established.

OR

TCA or BCA 80-90%

e. Apply a small amount only to warts and allow to dry until a white frosting develops; apply a baking soda paste to protect uninfected skin adjacent to treatment area.

f. Repeat weekly if necessary.

g. Inform the client that there will be 2-5 minutes of localized discomfort after application.

h. Avoid TCA contact with non-involved skin. Protection of uninvolved skin before application of TCA with Vaseline or zinc oxide is optional.

i. Later wash-off is not necessary as TCA evaporates quickly and is not systemically absorbed.

OR

Surgical removal by tangential scissor excision, shave excision, curettage, electrosurgery

Client Administered:

Podofilox 0.5% solution or gel: Clients may apply podofilox solution with a cotton swab or podofilox gel with a finger, to visible genital warts twice a day for 3 days, followed by 4 days of no therapy. This cycle may be repeated as necessary for a total of 4 cycles.

a. The total volume of podofilox should not exceed 0.5ml per day.

b. If possible, the health-care provider should apply the initial treatment to demonstrate the proper application technique and identify which warts should be treated.

c. Most clients experience mild-moderate pain or local irritation after treatment.

d. Safety during pregnancy has not been established.

OR

Imiquimod 5% cream: Clients should apply imiquimod cream with a finger at bedtime, three times a week for as long as 16 weeks. The treatment area should be washed with mild soap and water 6-10 hours after the application. Warts may resolve by 8-10 weeks or sooner.

e. Imiquod is a topically active immune enhancer that stimulates production of interferon.

f. Before wart resolution, local inflammatory responses are common; these reactions are usually mild - moderate.

g. Safety during pregnancy has not been established.

4. CDC Recommended Alternative Treatment Regimens for External Warts

See CDC 2006 MMWR Sexually Transmitted Diseases Treatment Guidelines, page 64.

5. Patients who may need referral to appropriate provider:

a. If lesions are visible in the vagina, on the cervix, or within the urethral meatus or anus.

b. Clients with massive lesions, which are not amenable to chemical treatment.

c. If lesions are atypical in appearance, and may require biopsy

E. Management of Sex Partners

1. Examination of sex partners is not necessary for the management of genital warts because the role of reinfection is probably minimal and, in the absence of curative therapy, treatment to reduce transmission is not realistic. Sex partners may benefit from examination to assess the presence of genital warts and/or other STDs.

2. Most sex partners of infected clients are already infected subclinically with HPV. The use of condoms can reduce, but not eliminate, the risk for transmission to partners who are likely to be uninfected (i.e., new partners); however, the period of communicability is unknown.

3. Sex partners should be cautioned that the client might remain infectious even though the warts are gone.

F. Education

1. The client must be given information on genital warts, which includes information on treatment.

2. The client should be told to abstain from intercourse if the treatment has caused external irritation. Use of condoms until all evidence of infection is eradicated may or may not be effective in preventing further spread of the disease.

G. Follow Up - Must be documented

1. The client should be asked to return in one week for re-evaluation. If an intense skin reaction is seen, subsequent treatments should be provided at 10-14 day intervals. Although allergies are very rare, an extremely severe reaction may be considered an allergy, and use discontinued.

2. If the first treatment is well tolerated, treatment can be given weekly.

3. If warts persist after 8 treatments, consideration should be given to other treatment modalities, i.e., cryotherapy.

4. Clients with abnormal Pap smears should be managed according to the guidelines outlined in the Pap Smear Screening and Follow Up protocol of this manual.

XI. Molluscum Contagiosum

A. Causative Agent

1. Molluscum contagiosum is caused by a pox-type DNA virus. It is spread by both sexual and non-sexual contact. The incubation period is from 2-7 weeks.

2. Symptoms include shiny, smooth, white, dimpled bumps, with a curd-like core and itching.

B. Examination/Diagnosis

1. History should include documentation of the following:

   a. Onset of symptoms

   b. Location of lesions - any itching or irritation?

   c. Any co-existing abnormal vaginal discharge?

2. Physical exam must include documentation of the following:

   a. Number and location of typical firm, small (1-5mm) pink, fleshy papules, often umbilicated.

      (1) White caseous material can be expressed on compression.

      (2) Umbilicated papule has a white central "pearl" when opened.

      (3) Inclusion bodies can be identified on a stained slide of the contents.

   b. Pelvic exam to rule out other co-existing infections.

3. Laboratory Procedures

   Offer screening for other STDs.

C. Treatment

1. Molluscum will go away on its own without treatment, usually within one year.

2. If a client has ten lesions or less, the clinician may choose to treat molluscum by removing the top of the molluscum with a sterile lancet and applying gentle pressure to remove the core of the lesion. The lesion should then be touched with a silver nitrate stick.

3. TCA can be used as outlined in the HPV section of this protocol, page 31.

D. Education

1. The client shall be provided with information about the infection.

2. Information about medications should be given as indicated.

E. Follow-Up

The client should be instructed that if the lesions become infected or increase in number, she should seek care from a dermatologist.

XII. Scabies

A. General Information

Scabies is a parasitic infection, which involves multiple areas of skin, producing intense itching.

B. Causative Agent

1. Scabies is caused by an ectoparasite, *Sarcoptes Scabiei*. Sensitization to Sarcoptes scabei must occur before pruritis begins. The first time a person is infected with scabies, sensitization takes a few weeks to develop. Pruritis might occur within 24 hours of a subsequent reinfestation.

2. Scabies in adults may be sexually transmitted, although scabies in children usually is not.

3. The incubation period is days to weeks.

C. Examination/Diagnosis

1. A presumptive diagnosis is made when a client with a history of recent exposure to scabies demonstrates the primary lesion, which is a burrow, or has characteristic pruritic, erythematous, papular eruptions. Excoriations and secondary infections are common. The pruritis is usually worse at night.

2. A definitive diagnosis is difficult to make and requires that the mite, its eggs, larvae, or feces be identified grossly or microscopically. Specimens are obtained by scraping papules or burrows. (This procedure is not recommended in our clinic sites.) Common sites of infection include the wrists, webbing between the fingers, the axillae, the penis, and inner thighs.

D. CDC Recommended Treatment Regimens

- Permethrin cream (5%)applied to all areas of the body from the neck down and washed off after 8-14 hours.

- Ivermectin 200 ug/kg PO single dose, repeated in 2 weeks **(not recommended for pregnant or lactating women)**

E. CDC Alternative Treatment

See CDC **2006** MMWR Sexually Transmitted Diseases Treatment Guidelines, page 79.

F. Management of Sex Partners and Household Contacts

1. Both sexual partners and close personal or household contacts within the preceding month should be examined and treated.

2. Sexual or close physical contact should be avoided until after treatment.

G. Education

1. Client should be given information about scabies and the medication prescribed.

2. Clients who do not respond to the recommended regimen should be re-treated with an alternative regimen.

3. Bedding and clothing should be decontaminated (i.e., either machine-washed or machine-dried using the hot cycle or dry-cleaned) or removed from body contact for at least 72 hours. Fumigation of living areas is unnecessary.

H. Follow Up

1. Pruritis may persist for up to two weeks after treatment. Some experts recommend re-treatment after 1 – 2 weeks for clients who are still symptomatic; other experts recommend re-treatment only if live mites are observed.

2. The client may be offered a recheck appointment in the clinic following therapy.

XIII. General Education Principle

A. Explore the client's feelings regarding diagnosis. Recognize potential reactions of fear, disbelief, anger and sadness.

B. Educate the client regarding nature and etiology of the suspected diagnosis, causative factors, and importance of accurate diagnosis and treatment.

C. Instruct the client on the risks of potential for other infections, risk of infertility, risk for life-threatening infections.

D. Advise the client of importance of notification of contacts and need for protection with current partner(s). Recognize difficulty in partner contact and explore this with patient. Offer client education materials; it may be useful to role play with client.

E. Advise the client to abstain from intercourse until she and partner(s) have completed treatment and instruct to use condoms until follow-up is complete, if compliance is doubtful. Provide a supply of condoms.

F. Provide both verbal and written information regarding need for future protection and follow-up instructions. Provide referral resources as needed for client's partner(s) and possible support group for client as appropriate.

XIV. Expedited Partner Therapy (EPT)

A. General Information

1. Contact referral conducted by either the partner or the provider has been an insufficient strategy in the management of positive Chlamydia and/or gonorrhea.

2. Based on the results of four randomized controlled trials, the CDC, in 2006, endorsed the use of expedited partner therapy (EPT) as a partner management strategy for patients with a lab-confirmed diagnosis of either Chlamydia or gonorrhea. The American Medical Association (AMA) has backed this endorsement.

3. The use of EPT in Colorado is done with the approval of both the Board of Pharmacy (Policy 40-4, July 19, 2007) and the Board of Medical Examiners (Policy 40-10, May1, 2001). These policies are included at the end of this protocol.

B. Client Selection

1. Partner(s) of a heterosexual client.

2. Client must have a lab-confirmed positive Chlamydia or gonorrhea diagnosis.

C. Contraindications

1. **Chlamydia or gonorrhea infections in men who have sex with men (MSM).**

2. **Client with STDs other than Chlamydia or gonorrhea.**

3. **Client with STD-associated syndrome (PID, MPC, NGU) without a lab-confirmed diagnosis of Chlamydia or gonorrhea.**

D. Procedure

1. **Client should be counseled to encourage her/his partner to present to clinic or private provider for testing and treatment; however, if partner(s) is not willing or able to be evaluated, then client should be encouraged to use EPT. If the client selects EPT, then the client should be counseled to tell the partner(s) to read all the information in the partner pack before taking the medication**

2. **EPT is carried out with the use of "partner packs." A client may be offered up to 3 (three) partner packs. Partner packs contain the appropriate treatment drug for either Chlamydia, gonorrhea, or both, information about the infection, and information about the medication(s) and how to take it. (Please see example partner pack information sheets at the end of this protocol.)**

3. **Any medication dispensed as EPT must be properly labeled and logged out in your pharmacy log. If possible, collect the partner name, date of birth, and phone number. If unable to collect this partner information, use "Partner #1," "Partner #2," or "Partner #3" for the log book and the label. Assign an Rx number as per usual, as well as provider name, lot#, expiration date, and instructions for use. Label is placed on the medication container. Please remember that if the partner is not a client of yours and has no record at your clinic (or other STD or Title X 340B eligible clinic), then use of drugs purchased at 340B pricing is not appropriate. Partner pack treatment drugs for non-clients should be dispensed from separate stock that was not purchased at 340B discounts.**

4. **Documentation in the client record must include whether EPT was offered, whether it was accepted, and how many and what type of EPT were given. Please see the example Expedited Partner Therapy (EPT) Check List included at the end of this protocol. If an agency chooses to use such a check list, then documentation in the client record should also indicate that this check list was completed and signed.**

5. **You, the provider, must report treatment of gonorrhea and Chlamydia to the STD Registry at the Colorado Department of Public Health and Environment using the morbidity reporting form included in this protocol (and also available on the Family Planning Program website listed #4 under Other Resources below).**

E. Other Resources

1. **http://www.region8ipp.com/epttoolkit/eptindex.htm**

2. **http://www.cdc.gov/std/ept/**

3. **http://www.cdphe.state.co.us/dc/HIVandSTD/EPT/index.html**

4. **http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html**

Colorado State Board of Pharmacy Policy

POLICY NUMBER: **40-4**

Title: Appropriateness of Labeling Prescriptions to Partners of Patients with Sexually Transmitted Infections

Date Issued: July 19, 2007

Purpose: To clarify the Colorado Pharmacy Board's position concerning the appropriateness of labeling prescriptions to partners of patients with sexually transmitted infections.

POLICY: The Board acknowledges the concern and dilemma which occurs when a pharmacist encounters a patient with a sexually transmitted infection, and the partner does not come to the physician's office to obtain a prescription order. The ideal situation would be that each partner visits his or her primary healthcare provider for treatment to obtain a prescription order. However, the Board recognizes that what is idealistic may not be realistic. There is compelling need for the partner to receive treatment in the form of prescription medications. Treating partners of patients with sexually transmitted infections is generally considered acceptable and desirable if the partner will not seek treatment from his or her primary healthcare provider. The overriding public policy concern must be to treat the infected partner. It must be made clear to the patient that his or her partner must take the medication as prescribed and should follow-up with his or her own healthcare provider. If the partner has any drug allergy or is on any medication, he or she should consult with a healthcare provider before obtaining the prescription. It is the position of the Colorado Pharmacy Board that the public risk of untreated sexually transmitted infection is greater than the risk of complications from dispensing in this less than ideal setting.

Therefore, the Board approves of the labeling of prescriptions for partners of patients with sexually transmitted infections pursuant to prescription orders issued by a licensed practitioner in the following manner:

1. Label the treated patient's prescription by the patient's own name.

2. Label the untreated partner's prescription by the treated patient's name immediately followed by the word "Partner". For example, for the treated patient – "Joe Smith", then for the untreated patient – "Joe Smith's Partner."

3. Assign a separate and unique identifying number to each prescription and clearly identify this number on each corresponding prescription label.

Colorado State Board of Medical Examiners Policy

POLICY NUMBER:	**40-10**
Title:	Appropriateness of Treating Partners of Patients with Sexually Transmitted Infections
Date Issued:	5/10/01
Date(s) Revised:	
Reference:	
Purpose:	To clarify the Colorado Board of Medical Examiners' position concerning the appropriateness of physicians treating the partners of patients with sexually transmitted infections.

POLICY: The Board acknowledges the concern and dilemma which occurs when a physician encounters a patient with a sexually transmitted infection, and the partner of the patient does not come to the physician's office. The ideal situation would be that each partner visit his or her primary healthcare provider for treatment. However, the Board recognizes that what is idealistic may not be realistic. There is compelling need for the partner to receive treatment in the form of prescription medications. Treating partners of patients with sexually transmitted infections is generally considered acceptable and desirable if the partner will not seek treatment from his or her primary healthcare provider. The overriding public policy concern must be to treat the infected partner. It must be made clear to the patient that his or her partner must take the medication as prescribed and should follow-up with his or her own healthcare provider. If the partner has any drug allergy or is on any medication, he or she should consult with a healthcare provider before filling the prescription. It is the position of the Colorado Board of Medical Examiners that the public risk of untreated sexually transmitted infection is greater than the risk of complications from prescribing in this less than ideal setting.